No. 11690

IN THE

United States Circuit Court of Appeals

FOR THE NINTH CIRCUIT

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET,

Appellants,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLANTS' BRIEF.

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Statement of Pleadings and Facts Re Jurisdiction.

The United States Government on March 18, 1947, filed an Information [R. 2] containing Counts I to VII in which both appellants were charged with "violation of the Federal Food, Drug and Cosmetic Act" (21 U. S. C. A. 331 and 333) in that they "did * * * unlawfully cause to be introduced and delivered for introduction into interstate commerce" drugs which were then and there adulterated and misbranded. Both appellants were found guilty on Counts I to IV inclusive and Count VII, and not guilty on Counts V and VI. Even though this was the first alleged offense of either appellant, the corporate appellant was fined $3,000.00 and the individual appellant Bavouset was placed on five years' probation [See Judgment R. 20 and Probationary Order R. 22, filed July 7, 1947].

Within the statutory period, and on July 16, 1947, both appellants filed their notices of appeal [R. 24, 25].

No jurisdictional questions arose in the Lower Court and it is believed that no jurisdictional questions will arise in this Court, this Court having authority to review the District Court's decision under 28 U. S. C. A. 225(a) and (d).

Concise Statement of Case.

Counts I and II, III and IV, and VII, each involve separate sets of facts which are briefly stated as follows:

Counts I and II, Indoform, Exs. 3 and 4.

As stipulated [R. 14], vials or bottles, Exs. 3 and 4, containing the product "Indoform" were shipped in interstate commerce on or about September 17, 1945, from Pasadena, California, to Dr. Joseph C. Bunten, Cheyenne, Wyoming. This vial was picked up on or about January 24, 1946, by Government inspector Ralph M. Davidson and was mailed to the Food and Drug Administration, Washington, D. C.

The Government contends that each cubic centimeter of this product did not contain three International Units of posterior pituitary, and that each cubic centimeter of this product did not contain 1 grain of thyroid substance, as set forth on the label, Ex. 4, on September 17, 1945, when it was introduced into interstate commerce.

On February 18, 1946, the contents of the vial, Ex. 3, were examined, and Arnold E. Mason, a pharmacologist and analyst of the Food and Drug Administration, Washington, D. C., testified that the tests he made showed practically no posterior pituitary in the product [R. 59].

The sole evidence introduced by the Government as to whether or not this product contained the amount of

posterior pituitary set forth on the label, Ex. 4, on September 17, 1945, the date it was introduced or delivered into interstate commerce, is an *opinion* expressed by Government's witness Mason in response to an *improper* hypothetical question, duly objected to, and which question included facts not proved and which question was based on the assumed existence of facts, the existence of which was not established by any evidence whatever in the case.

The Government introduced no evidence whatsoever to establish that physical changes did not occur in the goods after it was shipped by appellants; whether or not it was properly cared for; whether or not it had been exposed to excessive light; whether or not it had been protected from undue temperature variations; whether or not it had been tampered with; or whether it had been added to or otherwise adulterated by anyone between the time the goods left appellants' place of business and was introduced in interstate commerce, and the time the tests were made by Government witnesses.

The Government *erroneously* argues that the term "Thyroid Substance" on the label, Ex. 4, means that the product contains iodine; and that the product is misbranded and adulterated because the witness Buell, a chemist for the Food and Drug Administration at San Francisco, on March 27, 1946 [R. 85] tested the product for its organically combined iodine content [R. 87] and found none present [R. 89].

The Government witness Buell did not test this product for any "thyroid substance" other than iodine [R. 96]. He admitted, however, there could be other parts of the thyroid gland in solution [R. 94].

Appellants rebutted these contentions by the positive testimony of the appellant Bavouset, who testified of his own personal knowledge as to the compounding of the product and that the product contained three International Units of posterior pituitary and one grain of thyroid substance [R. 110]. The appellant Bavouset is a chemist and has had about twenty years experience in the pharmaceutical business [R. 108] and has been making Indoform, the product under discussion now, for about fifteen years [R. 109].

The evidence on behalf of the two appellants is that the label does not state that iodine is present; they freely admit that there never was any iodine in the solution; and that the Government and its witnesses are unwarranted in contending that iodine is represented to be present in the solution [R. 111].

The label, Ex. 4, specifies thyroid substance which is not the drug in the United States Pharmacopoeia known as "thyroid". The official definition of thyroid is "Thyroid is the cleaned, dried and powdered thyroid gland previously deprived of connective tissue and fat" [R. 136].

A disclaimer was put on the product stating that it did not contain therapeutically useful constituents, to definitely let the doctor know that the thyroid content was not the iodine content [R. 111]. The Government witness Buell admitted that the label indicated that there was no active substance of thyroid in the solution [R. 95].

Counts III and IV, Pluri-B, Exs. 6 and 7.

As stipulated [R. 15], the vial and label, Exs. 6 and 7, were shipped by appellants on July 16, 1945, to Dr. Clement Swaim, Reno, Nevada. The Government inspector Griebling picked up two vials and contents on

August 30, 1945, and shipped them to Food and Drug Administration, Washington, D. C.

The Government witness Capps on September 24, 1945 [R. 97] examined the contents of Ex. 6 and found that it contained thirty-three milligrams of thiamine hydrochloride instead of fifty milligrams, as stated on the label, Ex. 7 [R. 100].

This witness was then asked the improper hypothetical question in which it was assumed "* * * that the product received ordinary and reasonable care, and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather, * * *" none of which assumed facts are supported by any evidence whatever in the case [R. 100]. In response to said improper question Capps gave his opinion that on September 24, 1945, when shipped, the contents did not contain more than thirty-three milligrams of thiamine hydrochloride per cubic centimeter [R. 100, 101]. Thus the only evidence supporting the Government's case is the *opinion* of the Government witness Capps, based on an *improper* hypothetical question containing facts not proved.

As in the case of Counts I and II, there was no evidence whatsoever to prove that physical changes did not occur in the product *after* the date of shipment by appellants, or as to what happened to the product or with regard to the conditions to which it was exposed from the time it was shipped by appellants until tested by the Government, or as to whether or not the goods had been tampered with. The Government witness Capps testified that he did not make any examination of the cap of Ex. 6 to determine whether it had been punctured [R. 106]; in other words, tampered with.

Bavouset testified that thiamine hydrochloride will deteriorate if subjected to light or heat, if exposed to air over a period of time, etc. [R. 115, 149]. Dr. Icke also testified as to its instability under certain conditions [R. 159].

The appellant Bavouset testified with regard to Counts III and IV and particularly with regard to Exs. 6 and 7; that the contents were probably made by himself [R. 114]; that all of the materials set forth in the label were combined in the solution, and at the time the solution had the full strength and potency set forth on the label [R. 115].

Count VII, Pluri-B, Exs. 1 and 2.

As stipulated [R. 16, 17] a number of vials with labels, of which Exs. 1 and 2 are exemplary, were shipped by appellants on June 18, 1946, to Dr. P. M. Ryerson, Phoenix, Arizona. The Government inspector Kerr collected six vials and contents on or about July 12, 1946. and shipped them to Food and Drug Administration, Washington, D. C.

The Government witness Wiley received the samples, Ex. 1, on July 23, 1946 [R. 33], and upon inspection found that they were badly contaminated with undissolved material [R. 34]. The Government witness Wiley was then asked the *improper* hypothetical question, duly objected to, and in answer to which he gave his *opinion* that the "* * * undissolved material was undoubtedly present on June 18th when the material was shipped * * *" [R. 42].

The hypothetical question was bad and improper because it did not include a sufficient factual basis to support an opinion in that no mention whatever was made

of the conditions to which the drug had been subjected after shipment by appellants. Furthermore, even if the question was proper Wiley's opinion given in response thereto is not entitled to any weight whatever.

Wiley admitted that temperatures slightly above freezing would cause the material in solution to precipitate. As in the case of all of the other counts, there was no evidence whatever as to what happened to the product or with regard to the conditions of light, temperature, etc., under which it was kept from the time it was shipped by appellants from Pasadena, California, until tested by the Government's witness Wiley in Washington, D. C.

Bavouset testified that the precipitation might be due to fluctuation of temperature [R. 145]. Dr. Icke testified that the precipitation might have been due to conditions of temperature, or the addition of other substances into the vial [R. 171, 172].

There is no evidence that these particles do not constitute material which *was added* to the vials after the doctor received them. The Government stipulated that *doctors deliberately insert other things* into the bottles to make a different combination of a product [R. 168].

As Dr. Icke testified, it is impossible to say, without exact knowledge, just when the precipitation did occur.

The Government's unfounded and worthless opinion evidence, based on the improper hypothetical question, is most fully disproved by the testimony of the appellant Bavouset and the witness Smiley. Bavouset testified that there was no precipitate in the bottles at the time he made the product, that there was no precipitate in the bottles when they were shipped to Dr. Ryerson on June 18, 1946 [R. 118], and that control batches were kept

until after the material had been shipped [R. 119]. Mrs. Smiley, in charge of the shipping department, positively testified that there were no foreign particles in these vials when she examined them for that purpose when they were shipped [R. 121].

Specification of Errors.

Appellants will rely on all of the points or assigned errors contained in the STATEMENT OF POINTS WHICH APPELLANTS INTEND TO RELY ON THE APPEAL, PURSUANT TO RULE 19(6) OF THIS COURT, namely, I to XII inclusive. These points or assigned errors appear at pages 229 to 232 inclusive of the Record.

In the argument the assigned errors will be considered in certain groups to facilitate presentation of the argument.

Summary of Argument.

Appellants are guilty of a crime only if the drugs were adulterated or misbranded at the time they were introduced by appellants into interstate commerce. The Government failed to prove how the goods were handled, the conditions of temperature, light, etc., to which they were exposed, and what was done with them or to them.

There is considerable evidence showing that these drugs will change in potency (Counts I, II, III and IV) or precipitate (Count VII) if subjected to undue light, improper temperatures, etc., or if other materials are added to the contents of the vials, etc.

The Government failed to eliminate the possibility of the drugs having lost their strength (Counts I, II, III and IV) or having undissolved material formed or introduced in it (Count VII) between the dates of shipment and the dates of the Government tests [Specification of Errors X and XI, R. 232]. POINT ONE, *infra.*

The positive testimony of appellants proves that the drugs were properly labeled and of the proper potency and purity when shipped.

The Trial Court permitted the Government attorney to propound improper hypothetical questions to the Government expert witnesses, some of which questions did not include a sufficient factual basis necessary to support an opinion, and other hypothetical questions which assumed facts which were never proved—assumed facts with respect to which there is no testimony whatever in the Record. Appellants' attorney's objections to these improper questions were overruled and the Government's expert witnesses were permitted to give their opinions to the prejudice of appellants [Specification of Errors I, II and III, R. 229 to 231, inclusive].

It is, of course, well established law that in criminal cases the identity of the object must be established, and in Food and Drug cases it is necessary to have a factual basis upon which the Government expert can testify as to the condition of the goods when they were placed in interstate commerce. The Government must prove that no changes in the drugs occurred subsequent to their be-

ing placed in interstate commerce, and as a foundation for such proof it is absolutely necessary that the Government establish the facts which show the conditions to which the goods were exposed, that they were not tampered with, etc. In the absence of such evidence appellants' objections to the hypothetical questions should have been sustained. POINT TWO, *infra.*

Without these answers to the hypothetical questions there would not be in the Record even an opinion that the goods were adulterated or misbranded when they were introduced into interstate commerce. Thus it is clear there is no proper admissible evidence upon which a finding of guilty could be made against either of the appellants [Specification of Error IV, R. 231], and that the finding of guilty is contrary to law [Specification of Error V, R. 231].

The failure of the Government to prove how the drugs were handled, the conditions to which they were exposed, or what was done with them or to them, and the failure of the Government to eliminate the possibility of the drugs having lost their strength or having become impure between the dates of shipment and the dates of the Government tests, clearly shows that the Government certainly failed to prove its case beyond a reasonable doubt [Specification of Errors VIII and IX, R. 231, 232]. POINT THREE, *infra.*

The positive evidence of appellants proves that the drugs were properly labeled and of proper potency and

purity when shipped. The finding of guilty by the Trial Court is, therefore, contrary to the weight of the evidence [Specification of Error VI, R. 231]. This positive testimony should compel a holding that appellants are not guilty of committing any crime. POINT THREE, *infra.*

The Government has not proved adulteration or misbranding because of the absence of "thyroid substance" as charged in Counts I and II. The positive testimony of appellants proves that there was one grain of aqueously extracted thyroid substance per cubic centimeter of the product Indoform. POINT THREE, *infra.*

The test made by the Government witness Mason for posterior pituitary was inaccurate and worthless. Mason did not take into consideration the fact that Ex. 3 contained suprarenal cortex which contains adrenalin, and that adrenalin represses any tests which are made to show the presence of posterior pituitary. POINT THREE, *infra,* section entitled "The Test Made By Mason for Posterior Pituitary Was Inaccurate and Worthless."

ARGUMENT.

POINT ONE.

Specification of Errors X and XI. [R. 232.]

"X.

"The District Court erred in that the Government failed to eliminate the possibility of the products having lost their strength or potency through the failure or neglect of parties other than the defendants" [R. 232].

"XI.

"The District Court erred in that the Government failed to prove that heat, or light, or lack of refrigeration, or moisture did not in some way come in contact with the bottles so as to cause the alleged loss of strength" [R. 232].

Appellants are not guilty of the crime charged unless the drugs were "* * * when caused to be introduced and delivered for introduction into interstate commerce * * *"[1] "* * * was then and there adulterated within the meaning of 21 U. S. C. 351(c) * * *"[2] or "* * * was then and there misbranded within the meaning of 21 U. S. C. 352(a) * * *."[3]

The sole evidence of the Government to "prove beyond a reasonable doubt" that the drugs were adulterated or misbranded when placed in interstate commerce by appellants, are the opinions of its expert witnesses, which opinions are based on tests made after the drugs were picked up at the doctors' offices to whom the drugs were

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[1]These words are quoted from the counts of the information. See, for example, Count I [R. 3] starting at line 11 at the bottom of the page.

[2]Counts I, III, V and VII charge adulteration.

[3]Counts II, IV and VI charge misbranding.

shipped, and after the drugs had been shipped to Washington, D. C.

The Government's charge of adulteration and misbranding because of the absence of iodine from the Indoform, Exs. 1 and 2, as charged in Counts I and II, will be separately discussed under the section in POINT THREE entitled "Government Has Not Proved Adulteration or Misbranding Because of the Absence of 'Thyroid Substance' as Charged in Counts I and II."

We respectfully submit that the opinion evidence of the Government is absolutely worthless because the expert witnesses had no knowledge that the alleged adulteration or misbranding did not occur enroute to the doctor's office, or in the doctor's office, or in the hands of the Government inspectors who picked up the drugs, or enroute to Washington, D. C., when shipped there by the Government inspectors.

As this is a criminal case it was, of course, incumbent upon the Government to prove the charges in the information by evidence that satisfies beyond a reasonable doubt that the appellants were guilty of the charges.

Alberty v. United States (C. C. A. 9), 159 F. (2d) 278;

Von Bremen v. United States (C. C. A. 2), 192 Fed. 904;

George A. Breon & Co., Inc. v. United States (C. C. A. 8), 74 F. (2d) 4;

United States v. Commercial Creamery Co. (D. C. Wash.), 43 Fed. Supp. 714.

To establish its case the Government had to prove that the drugs did not change in potency or become impure after they were shipped by appellants.

In this type of case such evidence is usually given by the receiver of the drugs and by the Government inspector who collects the drugs, both of whom must testify as to how the drugs were handled and cared for while in their custody; otherwise there is no factual basis to support hypothetical questions such as were propounded to the witnesses, or to support the opinions given in response thereto.

These persons, or any persons who could testify as to how the goods were handled after being shipped by appellants, were not called by the Government, and evidence such as they might give is totally absent from this case.

Appellants sell their drugs only to doctors [R. 111]. The Government inspectors did not pick up the drugs from a drugstore where they are kept on shelves for open sale to customers and not for the druggist's own use. They were picked up at doctors' offices where doctors use these drugs in the treatment of their patients.

Not only is there a lack of evidence as to how the drugs were cared for after they were shipped by appellants, but, on the contrary, there are two important classes of evidence which establish beyond all doubt that the Government did not prove its case, and that the weight of the evidence is contrary to the Court's finding of guilty.

Stability of Appellants' Products Under Heat, etc.

In the first place, there is considerable evidence showing that these drugs will change in potency if not kept under proper conditions of temperature, light, etc., and if not properly handled.

Dr. Icke testified, with respect to the stability of thiamine hydrochloride (Counts III and IV), as follows:

> "Q. What would you assume to be above normal conditions on B-1 as far as temperatures are concerned?
>
> * * * * * * * *
>
> A. I would say that any temperature above 100 to 120 degrees Fahrenheit might be above what you would consider normal.
>
> Q. If the bottle was sealed as in that bottle, would you expect it to deteriorate within a matter of a few months down to only 33½ per cent? A. If that bottle had been setting in the sunlight so that the temperature got up high, or any other factor which might have elevated the temperature, it might have deteriorated." [R. 185.]
>
> * * * * * * * *
>
> "Q. Under what conditions is it not a stable product? A. Vitamin B-1 can be destroyed very rapidly if the solution is brought towards neutrality or on the alkaline side in a solution that must be kept acid in order to be stable. Also, it is susceptible to destruction by presence of sulfites, or it can be destroyed by oxidation, and in any of those cases that those agents were present which might cause destruction, any temperature above normal would speed the rate of destruction." [R. 159.]

He also testified that many doctors use isopropyl alcohol for sterilizing instruments and that even a small amount of isopropyl alcohol would affect the stability of the thiamine hydrochloride [R. 161, 163]. Dr. Icke also testified that air which contains oxygen would affect the stability of thiamine hydrochloride in that thiamine is susceptible to oxidation [R. 163].

Bavouset testified that thiamine hydrochloride [Counts III and IV, Exs. 6 and 7] will deteriorate if subjected to light or heat, or if exposed to air over a period of time, or if the degree of acidity of the solution is changed from pH 3.2, and that if the solution becomes neutral, the thiamine hydrochloride dissipates very rapidly [R. 115, 149, 150].

With respect to the undissolved material in Ex. 1 (Count VII), Dr. Icke testified that riboflavin might precipitate if the doctor added other material, changing the nature of the solvent, and that temperature would affect its stability, particularly if any oxidizing materials or any substance which increased the alkalinity of the solvent were introduced into the solution [R. 171, 172].

Wiley stated that temperatures slightly above freezing would hasten or increase precipitation [R. 42].

Bavouset testified that he has noticed that riboflavin precipitates upon fluctuation of temperature [R. 145].

Addition of Other Things Into Products.

In the second place, the evidence shows that doctors insert hypodermic needles into the caps of these bottles for withdrawing the solution from them, and that it is possible and likely that the potencies of the solutions will be changed because of the presence of isopropyl alcohol

which some doctors use for sterilizing hypodermic needles, or the hypodermic needles themselves [R. 162].

Dr. Icke's testimony on this point is on pages 161, 162 and 163 of the Record and reads as follows:

"Q. Are you familiar with the methods used by doctors in their offices? A. Yes, sir.

Q. In handling bottles, hypodermic syringes, etc.? A. Yes.

Q. Do doctors sterilize their syringes and needles before they take out doses of medicine from bottles of that kind? A. It is the common practice to sterilize them, yes.

Q. And what things are used for that purpose? A. Well, sometimes they use steam sterilization, or heating the things in boiling water. Others may use bichloride of mercury or various other bacteriacides. Also, it has become more and more common in recent years to use isopropyl solutions for sterilizing instruments.

Q. Before a bottle of that character is used for the purpose of withdrawing a dose of medicine is it customary to sterilize with some substance the cork before the needle is inserted? A. Yes. The doctor usually takes a piece of cotton or gauze and wipes off the top of the cap with alcohol, isopropyl alcohol is often used.

Q. If any of that isopropyl alcohol was left in the needle and went into the bottle would it affect the content or the potency of the thiamine hydrochloride? A. It might, because isopropyl alcohol is known to contain bacteriacides under many conditions. I have worked in a chemical laboratory at the time that discovery was made and observed the experimental work of the investigator, who showed that

isopropyl alcohol often contains bacteriacides. And I have also seen doctors taking solution to be injected from this bottle in which they have used isopropyl alcohol to sterilize their needle and syringe, and often, instead of drying the needle and syringe, they may just put the needle onto the syringe and move the plunger back and forth to pass a little air through it and get rid of most of the sterilizing agent. But I have seen them insert a needle into a bottle and which it was not completely dry, and because of their practice, introduce air into it. It would be possible for a spray of a small amount of isopropyl alcohol, and, therefore, bacteriacide, to be introduced into that bottle.

Q. And would the amount that would be so introduced affect the thiamine hydrochloride in the bottle? A. It would depend entirely on how much bacteriacide was in the isopropyl alcohol, how many injections had been withdrawn from the bottle, and how much bacteriacide was there just how much it would affect it. But even a small amount would affect it.

The Court: Immediately?

The Witness: The effect would start immediately; yes."

In addition to this we have the stipulation, and we believe this is very important, of the Government that the doctors deliberately insert other things into bottles to make a different combination of a product.

"Q. Do they ever deliberately insert other things into bottles to make a different combination of a product?

Mr. Neukom: Your Honor, I will stipulate that they do." [R. 168.]

The Government witness Capps admitted that he made no examination of the cap on Ex. 7 to determine whether or not it was punctured in any way, other than by just looking at it [R. 106]. Dr. Icke's testimony is that you can't tell whether or not a cap has been punctured by looking at it just with the naked eye [R. 161].

Government witness Mason was asked by the Court if the cork was sealed in the bottle, Ex. 5, in any way, and he stated, "I do not remember whether it was sealed into the bottle or not. * * *" [R. 78]. Also, the Government witness Mason, after testifying it was common practice for doctors to pass a hypodermic needle through the rubber cork [R. 79], testified that he did not examine the cork to determine whether or not it had been punctured by a needle (hypodermic needle), he stated he did not make an independent investigation on that point [R. 80].

The Government witness Mason took the stand on rebuttal and contradicted his original testimony by stating with regard to Ex. 3, "The vial was full and the rubber stopper or cork was protected, with a celluloid seal around it when I received it. It appeared as if it had never been opened." [R. 215.] After his testimony to the contrary this later testimony certainly does not establish the facts and does nothing more, it is submitted, than detract from the weight of any of Mason's testimony.

In this connection please see *United States v. Lord-Mott Co.*, 57 Fed. Supp. 128, in which the Court states at page 132:

> "* * * But the Court can not blink the fact that they (the witnesses for the Government) are naturally interested, or biased, in seeing that their work or the work of their associates in this matter is upheld, * * *." (Parenthesis added.)

Thus your Honors will see that if the drugs were not properly handled, or if the hypodermic needles used contained certain chemicals, or if the doctors from whose offices the drugs were picked up had injected other things into the bottles to make a different combination, it is quite likely that the potencies and conditions of the products changed at that time.

In addition to this there is no evidence that the Government inspector properly handled the drugs after he picked them up. Anyone of the above things may have occurred even while in the inspector's hands, or during shipment by the inspector to Washington, D. C.

The probabilities and possibilities mentioned above become even more important in view of the testimony ot the appellant Bavouset and appellants' witnesses Smiley, whose testimony establishes that when the materials were compounded they were of the potencies specified on the labels, and when shipped were inspected for the presence of impurities. Point Three, *infra.*

It seems quite reasonable to conclude, in view of these facts, that the drugs were not adulterated or misbranded when shipped, and the Court must reach the conclusion that the Government has not established its case nor carried the burden required in criminal cases.

The Court cannot assume that the various things which might happen to the drugs did not occur. This is a criminal case. There is imposed on the Government the burden of proving its case beyond a reasonable doubt, and the legal decisions hold that the Government has not proved its case beyond a reasonable doubt, unless it proves that the object or thing introduced in evidence was in the same condition at the time when the Government tests

were made, as it was at the time of the occurrence of the crime charged, namely, in this case, at the time the goods were introduced into interstate commerce.

Law re Goods Being of Same Potency and Condition When Tested as When Shipped.

In *United States v. S. B. Penick & Co., et al.,* 136 F. (2d) 413, the Circuit Court of Appeals for the Second Circuit upheld the conviction by the Lower Court and rejected the argument of appellants that the Government had not proved that the samples tested by the Government were the same drugs as introduced into interstate commerce. In that case the Court said:

> "* * * It is true that before a physical object connected with the commission of a crime can properly be admitted in evidence, there must be a showing that such object is in substantially the same condition as when the crime was committed. 2 Wharton, Criminal Evid., 11th Ed., § 757. * * * In each case the trial judge before he admits it in evidence must be satisfied that in reasonable probability the article has not been changed in important respects. Wigmore, Evidence, 3d Ed., § 437 (1); 32 C. J. S., Evidence, § 607. *In reaching his conclusion he must be guided by the nature of the article, the circumstances surrounding the preservation and custody of it, and the likelihood of intermeddlers tampering with it.* * * *" (Italics added) (p. 415.)

The Circuit Court, after these quotations, pointed out that in that case when the goods were received by the party to whom they were shipped by appellants, *samples* were taken and *preserved* and that it was a part of these samples which were obtained and tested by the Government witnesses. Thus in the *Penick* case the Government

introduced evidence which showed that the drugs were properly cared for and thus, by such evidence, excluded the possibility that the drugs became adulterated or misbranded after appellants had introduced them into interstate commerce.

Another case is *United States v. Buffalo Pharmacal Co., Inc.,* 131 F. (2d) 500, wherein the Circuit Court of Appeals for the Second Circuit upheld the conviction of one of the appellants because there was some evidence to indicate that the bottle of digitalis in question had been properly cared for. In that case evidence was introduced by appellants to show that digitalis, if not properly cared for, might deteriorate. The Government, to meet this evidence, showed that the goods were properly cared for. The Court said:

> "* * * While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, *there was some testimony to indicate that the bottle in question had been properly cared for.* We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding." (Italics added) (p. 502.)

In this case there is absolutely no evidence whatsoever that the drugs shipped by appellants were properly cared for or used by the doctors who received them or by the Government inspectors who picked them up.

In *Novak v. District of Columbia,* 49 A. (2d) 88, the Court stated at page 90:

> "* * * We agree that it was still incumbent upon the government to prove that the specimen taken from defendant and the one analyzed by the

chemists, and reported on in court, were the same and were in substantially the same condition when tested as when taken. * * *"

32 Corpus Jurus Secundum, Section 607 at page 458, reads in part as follows:

"In order that an article may be introduced it must be satisfactorily identified, and it must also be shown to the satisfaction of the Court that no such substantial change in the article exhibited as to render the evidence misleading has taken place. * * *"

"*Samples.* Samples are admissible on an issue as to the properties or qualities of the substance or articles involved in the case. The samples must be sufficiently identified as to their source, and must reflect the condition of the substance or articles as of the time involved in the issues. * * *"

In *Gutman v. Industrial Com.,* 50 N. E. (2d) 187, the Court held at page 188:

" 'It must appear, as a preliminary to the introduction of any object in evidence, that it has not sustained any substantial change by reason of lapse of time or otherwise, since the time in issue.' 20 Am. Juris 602, Section 719."

In *Rosa Alma Kees v. Canada Dry Ginger Ale, Inc.,* 199 S. W. (2d) 76, the defendant sold carbonated water to a grocer. The bottles were placed on a shelf in the grocery store, and the store was so arranged that the customers could wait on themselves. The owner of the store, Lovell, said that he was there most of the time, that nothing in the store ever froze, and that the bottles had not been tampered with.

The plaintiff who bought two bottles took them home, and in handling they exploded and she was very seriously injured. She brought suit against the defendant bottling company and tried her case under the *res ipsa loquitur doctrine.* In connection with this doctrine the Court stated as follows:

> "* * * This doctrine is a rule of evidence that relates to the mode of proof and is applicable where there has been an unexplained accident, and the instrument causing the injury was under the management or control of the defendant and, in the ordinary course of events, the accident would not have happened if the defendant had used due care. The unexplained circumstances may, in a particular case, warrant an inference of negligence. The doctrine has been extended to apply to cases involving an exploding bottle of beverage where it is shown that the condition of the bottle was not changed after it left the bottler's possession and prior to the occurrence causing the injury. When all intervening causes have been eliminated then, in effect, the bottle is still regarded as though it continued to remain in the hands of the bottler. (See *Stolle v. Anheuser-Busch, Inc.,* 271 S. W. 497; *Tayer v. York Ice Machinery Corp.,* 119 S. W. (2d) 240, 244.) In *Hughes v. Miami Coca Cola Bottling Co.,* 19 So. (2d) (Fla.) 862, 864, the court said: 'So far as we have been able to find from a study of the decisions, no court has ever held that recovery may be had in such cases, under the *res ipsa loquitur* doctrine, without an affirmative showing on the part of the plaintiff that after the bottle left the possession of the bottler it was not subjected to any unusual atmospheric changes or changes in temperature, or that it was not handled improperly up to the time of the explosion'." (pp. 76, 77.)

After discussing the retailer's testimony and holding that there is no question but that "Lovell should not have been permitted to testify that the bottles were not tampered with while in his store and that the bottles and caps were not changed while in his store." on the ground that "in these matters the witness was indulging in mere speculation, guess and conclusions," the Court, in reversing the lower Court, held:

> "* * * The bottle may have been frozen or subjected to extremely cold temperature before it reached Lovell's store. It may have been dropped, cracked, tampered with or mishandled by the customers or the employees while it was on the shelf in Lovell's store. It was there approximately 30 days. Certainly the jury was required to indulge in guess and speculation in finding that between the time that the bottle left the possession of the defendant and when it came into possession of the plaintiff it was not subjected to any condition that would tend to bring about the explosion resulting in plaintiff's injury. * * * citing cases * * *." (p. 79.)

See also *Pilot Life Ins. Co. v. Wise* (C. C. A. 5), 61 F. (2d) 481, at page 483.

POINT TWO.

Specification of Errors I, II and III [R. 229, 230, 231].

"I.

"The District Court erred in overruling defendants' objection to the latter of the following questions propounded to the witness Wiley:

'Q. By Mr. Neukom: Dr. Wiley, taking the two vials, part of Government's Exhibit No. 1, which I understand you examined about six weeks after the shipment in question here, from your knowledge of sterile solutions and from your observation of sterile solutions, your experience, are you able to express an opinion to this court as to whether or not the contents of those two vials, Government's Exhibit 1, did contain the undissolved particles you noticed there then as of the date they were shipped, namely, on or about June 18, 1946? Your answer is yes or no.'

* * * * * * * *

'Q. By Mr. Neukom: Will you please relate your opinion?' [Rep. Tr. of Proceedings, p. 17, lines 9 to 18, and p. 18, lines 17 and 18.]" [R. 229, 230.]

"II.

The District Court erred in overruling defendants' objections to the following questions put to the witness Mason:

'Q. Assuming, Mr. Mason, that this product was not exposed to excessive temperatures, that is to say, that you said was 212 degrees is the destructive temperature; and assuming the product was handled in a normal and careful manner, retained in the bottle, as Government's Exhibit No. 4, I believe; assuming which bottle you opened and conducted the tests as you have testified; and, with the assumption of what you found or did not find at that time, have you an opinion as to whether or not this product contained

three international units of posterior pituitary on September 17, 1945?'

* * * * * * * *

'Q. By Mr. Neukom: Now assuming that all that you have testified to here and the explanations you have given, what is your opinion, carrying on the assumptions that I have enumerated—what is your opinion as to the amount, if any, of posterior pituitary was in the product on or about September 17, 1945?' [Rep. Tr. of Proceedings, p. 61, lines 16 to 25, and p. 62, lines 6 to 10.]" [R. 230.]

"III.

The District Court erred in overruling defendants' objections to the following questions put to the witness Capps:

'Q. Now, assuming that the product received ordinary and reasonable care, and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather, and basing upon what you found on September 24, 1945, the amount of the B-1 or thiamine chloride that you found, have you an opinion as to what percentage or what amount that product, substance, or solution had on or about July 16, 1945, the date it was originally shipped?' [Rep. Tr. of Proceedings p. 94, lines 12 to 19.]" [R. 231.]

It was prejudicial error for the Trial Court to allow the Government's witnesses to answer these hypothetical questions. The appellants were seriously prejudiced thereby, particularly since there is no other competent evidence to sustain a conviction.

Subtract from the evidence these improper hypothetical questions and the unfounded opinion answers given in response to them, and what evidence of guilt is there? Absolutely none.

The first of said improper questions (Specification of Error I) was in connection with Ex. 1 (Count VII) and was directed to the witness Wiley. These questions appear on pages 41 and 42 of the Record. The objection appears on page 41 of the Record and is as follows:

> "Mr. Stick: I object to that, your Honor, upon the ground that until the conditions under which these bottles have existed or to which these bottles and contents have been subjected since the date that they were put into interstate commerce on June 18th must be before this witness before he can express an opinion as to whether or not the contents that are in there now were in the condition that it is now, going back to June 18th when it was shipped." [R. 41, 42.]

These hypothetical questions were bad and improper in that they did not contain sufficient facts to afford ground for a reasonable conclusion or opinion.

The record is clear that the riboflavin in Ex. 1 will precipitate if subjected to coolness, temperature fluctuations, if foreign material is added, etc. (POINT ONE, *supra*) and yet no mention whatever is made in said hypothetical questions with respect to the conditions to which Ex. 1 was subjected.

Law re Hypothetical Question Presenting Sufficient Facts to Afford Ground for Reasonable Conclusion.

> "* * * Purely abstract or theoretical questions and those too vague or indefinite to permit the witness to form a judgment of any value should be excluded. * * * A question is ordinarily improper where it does not present sufficient facts to afford ground for a reasonable conclusion."
>
> 32 Corpus Juris Secundum, Section 551.

In *Bickford, et al. v. Lawson,* 27 Cal. App. (2d) 416, 81 P. (2d) 216 at pages 222 and 223, the Court applied this rule of law as follows:

> "Where the facts related in the hypothetical question omit material undisputed evidence necessary to a fair, intelligent and sound opinion of the witness regarding the problem to be determined, it is not error for the court to sustain an objection thereto. The chief test of the competency of a hypothetical question which seeks to elicit the professional opinion of a physician regarding the treatment of a patient is whether it is a full and fair recital of all the essential evidence disclosed by the record on the particular issue which is involved. Where the question assumes facts in direct conflict with the undisputed evidence, or omits material facts upon which a determination of the problem depends, the hypothetical question becomes misleading and it is then likely to lead the witness to a false conclusion, and should be rejected. * * *"

See also:

> *Harrison v. United States* (D. C. Pa.), 49 F. (2d) 948 at page 949.

See also *Lawrence v. Butler,* 240 Pac. 840, 79 Cal. App. 436. In this case a truck damaged plaintiff's automobile after slipping down hill from oil in the street. Objections to hypothetical questions as to whether the truck would slide back if effective brakes were applied were *held* to have been properly sustained, since the element of the greasy condition of the pavement was not included.

The second of said improper questions (Specification of Error II) was in connection with Ex. 3 (Counts I and II) and was directed to the witness Mason. These questions appear on pages 75 and 76 of the Record. The objection

appears on pages 74 and 76 of the Record and is as follows:

> "Mr. Stick: I object to that as a matter that cannot be testified to by this gentleman, unless all of the conditions and factors under which this matter was kept, handled and existed between the time when it was shipped by the defendant to the time when he first saw it is also before him." [R. 74.]

This hypothetical question was bad and improper in that it included facts which were assumed, which assumed facts are not supported by any evidence whatever in the case. There is no evidence whatever in the case that the "* * * product was not exposed to excessive temperatures * * *" or that it "* * * was handled in a normal and careful manner * * *" [R. 75].

The third of said improper questions (Specification of Error III) was in connection with Ex. 5 (Counts III and IV) and was directed to the witness Capps. This question appears on pages 100 and 101 of the Record.

This hypothetical question, like the second one, was bad and improper in that it included facts which were merely assumed and which were not supported by any evidence whatever. The record is entirely devoid of any evidence whatever to the effect that the "* * * product received ordinary and reasonable care and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather, * * *" [R. 100].

In fact, there is no evidence whatever as to the conditions to which any of the products were exposed, or what was done to or with any of them from the time the products were introduced into interstate commerce at Pasadena, California, until tested by the Government witnesses at Washington, D. C.

Furthermore, the evidence clearly shows that these products, Ex. 3 (Counts I and II) and Ex. 5 (Counts III and IV) will deteriorate if subjected to heat, light or air, or if other substances are added thereto. (POINT ONE, *supra.*)

Law re Hypothetical Question Must Be Based on Facts in Evidence.

The applicable law was stated by this Court in the case of *Travelers Ins. Co. v. Drake,* 89 F. (2d) 47, at page 50, as follows:

> "* * * When the question assumes a state of facts which the evidence directly, fairly, and reasonably tends to establish, and does not transcend the range of the evidence, it is not objectionable. Denver & R. G. Ry. Co. v. Roller (C. C. A.) 100 F. 738, 49 L. R. A. 77; Proechel v. U. S. (C. C. A.) 59 F. (2d) 648. * * *."

In *Philadelphia & R. Ry. Co. v. Cannon* (C. C. A. 3), 296 Fed. 302, the Court held at page 306 as follows:

> "* * * It scarcely needs the citation of authorities to sustain the proposition that a hypothetical question calling for expert opinion must be based on facts in evidence. We are of opinion, therefore, that the question was improperly framed and the answer erroneously admitted. * * * (citing cases) * * *."

In *North American Accident Association v. Woodson* (C. C. A. 7), 64 Fed. 689, the Court stated on pages 691, 692 and 695, as follows:

> "Seven assignments of error, numbered from the fifth to the eleventh, inclusive, relate to the admission of evidence of expert witnesses concerning the cause of Dr. Kemper's death, in answer to hypothetical questions framed upon a supposed state of

facts not appearing in evidence at the time the questions were put, and not proven at any time on the trial. This testimony, against defendant's objection was introduced by means of depositions which had been taken before the trial, mainly in the state of Missouri. Several physicians residing in Missouri were examined, and their testimony taken, presumably on the supposition that the supposed facts upon which the answers were predicated would be proven by means of other witnesses on the trial. Some of these facts were proven, while others were not, but the answers were admitted by the court, the same as though all the facts stated in the hypothetical questions had been proven. This we think was error for which the judgment must be reversed. * * *" (pp. 691, 692).

"* * * It is a proposition too simple to require any citation of authorities that the material facts assumed in a hypothetical question must be proven on the trial, or rather that there must be evidence on the trial tending to prove them. Otherwise, it is error to allow them to be answered. * * *" (p. 695).

Jones, "The Law of Evidence in Civil Cases" (4th Ed), Section 371, page 694, states the applicable rule of law as follows:

"If there is no testimony in the case tending to prove the facts which are assumed by the hypothetical question, such question is improper."

See also:

32 Corpus Juris Secundum, Sections 551 and 552:
Henkel v. Varner (U. S. Court of Appeals, D. C.), 138 F. (2d) 934.

Hypothetical Questions Were Also Improper in That an Expert Witness Cannot Give His Opinion Upon the Very Question in Issue.

The testimony of expert witnesses is, of course, subject to the general rule excluding the opinions of experts as to the ultimate issues of fact to be determined. All of the hypothetical questions violated that rule of law and were therefore bad and improper. Appellants' attorney's objections to said questions should have been sustained on that ground, if for no other reason.

United States v. Spaulding, 293 U. S. 498, in which the Court held at 506, 507, as follows:

> "* * * The medical opinions that respondent became totally and permanently disabled before his policy lapsed are without weight. * * * Moreover, that question is not to be resolved by opinion evidence. It was the ultimate issue to be decided by the jury upon all the evidence in obedience to the judge's instructions as to the meaning of the crucial phrase, and other questions of law. The experts ought not to have been asked or allowed to state their conclusions on the whole case. (Citing cases.)"

See also:

United States v. Stephens (C. C. A. 9), 73 F. (2d) 695, 701;

United States v. McCreary (C. C. A. 9), 105 F. (2d) 297, 299;

Farris v. Interstate Circuit (C. C. A. 5), 116 F. (2d) 409.

POINT THREE.

Specification of Errors IV, V, VI, VII, VIII and IX Inclusive [R. 231, 232].

"IV.

The District Court erred in that there is no evidence in this case upon which a finding of guilty could be made against either of the defendants." [R. 231.]

"V.

The District Court erred in that the finding of guilty is contrary to law." [R. 231.]

"VI.

The District Court erred in that the finding of guilty is contrary to the weight of the evidence." [R. 231.]

"VII.

The District Court erred in that the finding of guilty is not supported by substantial evidence." [R. 231.]

"VIII.

The District Court erred in that it did not give defendants the benefit of reasonable doubt which they were legally entitled to." [R. 231.]

"IX.

The District Court erred in that the evidence in this case did not demonstrate beyond a reasonable doubt the defendants' guilt." [R. 232.]

There Is No Admissible Evidence in the Case to Sustain the Finding of Guilty.

Even without any evidence on behalf of appellants, the Government failed to prove its case. At the close of Government's case the sole evidence of guilt was the unfounded opinion answers to Government's hypothetical questions which assumed facts not supported by any evi-

dence whatever, or which did not include sufficient facts to support an opinion answer.

As we have shown in POINT TWO, *supra,* appellants' attorney's objections to these questions should have been sustained, and it was prejudicial error for the Trial Court to allow the Government's witnesses to answer these improper questions.

Furthermore, even if the questions directed to the witness Wiley (Count VII) were proper, his answers thereto are not entitled to any weight whatever. These questions were bad and improper for the reason that they did not include a sufficient factual basis to support an opinion in that no mention whatever was made with regard to the conditions to which the product had been subjected. (POINT TWO, *supra.*)

In connection with this Count, it should be noted that there is no evidence in the case as to what the undissolved material in Ex. 1 is. Dr. Thienes testified he could not tell what the precipitate was without chemically testing the precipitate [R. 54]. As a matter of fact, there is no evidence that the particles in Ex. 1 are precipitates; there is no evidence that these particles do not constitute material which was added to the vials after the doctor received them.

Wiley testified that Ex. 1 (Count VII) was twenty times over-saturated [R. 46]. He based this statement upon the solubility of riboflavin in water. He failed to take into consideration the fact that Indoform (Ex. 1) contains nicotinamide which is a very fine solvent for riboflavin and very definitely increases the solubility and stability of the riboflavin [R. 145]. In other words, the solvent is not the pure water, but a solution containing

other materials besides riboflavin and water [R. 167]. Some products have as much as 5.3 milligrams of riboflavin per cubic centimeter of solution [R. 167]. Ex. B, a competitor's product, contains 4 milligrams of riboflavin per cubic centimeter [R. 167].

In the light of the other substances in Ex. 1, as Dr. Icke stated, the two milligrams of riboflavin were not an excessive amount and it was not a supersaturated solution of riboflavin [R. 170].

As Dr. Icke testified, "* * * It would be impossible to say, without exact knowledge, just when that precipitation did occur. * * *" [R. 170]. As shown in POINT ONE, *supra,* the undissolved material in the product might be due to any one of a number of factors, and undoubtedly first appeared after the product was shipped.

As we have shown in POINT ONE, *supra,* there is no evidence as to how the products were handled or of the conditions to which they were subjected. Furthermore, there was no evidence precluding the possibility that the drugs became adulterated and misbranded at some time after they had been shipped by appellants from Pasadena, California [Specification of Errors X and XI, R. 232].

There was no proper or admissible evidence in this case upon which a finding of guilty could be made against either of the appellants. As a matter of fact, there is no proper evidence supporting the Lower Court's findings of guilty [Specification of Errors IV, VI and VII, R. 231]. The Lower Court's findings of guilty were most certainly contrary to law, which requires proof beyond a reasonable doubt [Specification of Errors V, VIII and IX, R. 231, 232].

Appellants Proved by Positive Evidence That Products Were Not Adulterated or Misbranded When Introduced Into Interstate Commerce.

At the conclusion of the Government's case, appellants were entitled to a dismissal; but in order to show by positive evidence that the drugs were not adulterated or misbranded at the time they were introduced into interstate commerce, appellants produced witnesses who testified of their own personal knowledge as to the compounding of the drugs and their condition at the time of shipment.

With respect to Exs. 3 and 4 (Counts I and II), the appellant Bavouset testified that he personally made a quantity of Indoform [R. 109] and when he made it it contained all of the ingredients specified on the label. He said:

> "Q. And this was one of several that were shipped to him. At the time that that was shipped was there three international units of posterior pituitary in a cubic centimeter of the contents of that bottle? A. Yes. I measured out that amount for this particular solution.
>
> "Q. And was there one grain of thyroid substance in that matter at that time? A. There was aqueously extracted one grain per cc of thyroid" [R. 110].

Bavouset testified that he probably made Ex. 6 (Counts III and IV), stated in detail how all of the materials named on the label were combined in the solution, and at that time the solution had the full strength and potency that is set forth on the label [R. 114, 115].

With regard to Ex. 1 (Count VII) Bavouset testified:

> "Q. I will ask you to look at the two bottles in Exhibit 1, look through them. Do you see anything

in those bottles other than the liquid solution? A. Yes; there is a precipitate.

Q. Was that precipitate in those bottles at the time you made it? A. No; it was not.

Q. Or when you finished making it? A. No; it was not.

Q. Was that precipitate in those bottles when you shipped it to Dr. Ryerson on June 18, 1946? A. No; it was not.

Q. Before any of these materials are shipped have you any means in your office of checking these products? A. We keep control batches for a short time after the material has gone out of the business, or the place of business.

Q. Are there any inspections made at the time they are shipped out? A. Yes; a very careful inspection is made the last thing before it is placed in shipping cartons and sent out and marketed" [R. 118, 119].

Mrs. Smiley testified that she is employed at Pasadena Research Laboratories, in charge of the shipping department, and was so employed on June 18, 1946 [R. 120]. Mrs. Smiley checks the solutions in the vials to be sure there are no foreign particles before the vials are put on the invoice on another table for the next girl to package and ship out [R. 120, 121]. Mrs. Smiley positively testified that there were no foreign particles in the vials, Ex. 1, (Count VII) when she examined them for that purpose, by means of an inspection lamp, at the time they were shipped [R. 121]. Mrs. Smiley believes she recalls this particular shipment because it is unusual to have an order as large as fifty bottles [R. 122].

Thus, we have only the Government's unfounded, improper, valueless opinion evidence, which is thoroughly

disproved by fact evidence of appellants. Thus we can see only one conclusion, namely, that the findings of guilty by the Lower Court are contrary to the weight of the evidence; or that there is no evidence to support the Lower Court's findings of guilty and that the Government utterly failed to establish its case beyond a reasonable doubt.

Government Has Not Proved Adulteration or Misbranding Because of the Absence of "Thyroid Substance" as Charged in Counts I and II.

We are arguing this charge separately because the Government takes the position that the label, Ex. 4, on the Indoform vial represents that iodine is present, and the Government witness Buell made a test for iodine and found none. It is appellants' position that the label does not indicate that iodine is present, but, on the contrary, clearly indicates that iodine is not present, and appellants furthermore admit that there never was any iodine in the sterile Indoform solution.

It is appellants' position, and we believe it is well supported by the facts, that in the absence of proof beyond a reasonable doubt there was not *any* thyroid substance present, the appellants must be found not guilty.

The label, Ex. 4, states that each cubic centimeter contains "Thyroid Substance 1 gr." and bears the notation, "This preparation does not contain any known therapeutically useful constituent" [R. 63].

The Food and Drug Act distinguishes between an "official drug" which is one defined in the Official Compendium, namely, the United States Pharmacopoeia, and an "unofficial drug" which is not defined. 21 U. S. C., Section 351(b) refers to the so-called official drug and a

person is guilty of an offense if the drug differs from the standards set forth in the Pharmacopoeia. In this present case, however, appellants are not charged with the violation of 21 U. S. C., Section 351(b). "Thyroid substance" is not an official drug. It is an unofficial drug. Appellants are charged with a violation of 21 U. S. C., Section 351(c), which states that a drug shall be deemed to be adulterated if "its strength differs from, or its purity or quality falls below that which it purports or is represented to possess" (21 U. S. C., Sec. 351(c)).

The crime charged is that this drug, sterile Indoform solution, was adulterated because at the time of shipment it was represented to contain "thyroid substance 1 gr. (per cc), * * * whereas, in fact and in truth, each cubic centimeter of said drug * * * did not contain 1 grain of Thyroid Substance but did contain no Thyroid Substance" [Count II, R. 4, 5].

The sole question then is "did this drug contain one grain per cubic centimeter of thyroid substance as set forth on the label when it was shipped," which thyroid substance "* * * does not contain any known therapeutically useful constituent" [Label, Ex. 4, R. 63]. The Government did not prove beyond a reasonable doubt that one grain of thyroid substance per cubic centimeter was not present. The only thing the Government attempted to prove was that there was no iodine present.

The Government's expert witness Buell did not test to determine the presence of any thyroid substance, other than that one substance, namely, iodine:

> "A. The only thing I examined it for was for the therapeutically active ingredients of thyroid, which were the organically combined iodine products" [R. 95].

The label on the vial does not represent that iodine is present. The label unequivocally states that the preparation does not contain any known therapeutically useful constituents. Thus the label itself indicates that iodine is not present for the very reason that iodine is a therapeutically useful ingredient. Thus it is futile for the Government's witness to test for iodine. The Government should have tested the solution for the other thyroid substances.

The Government witness Buell admitted that there are fats, proteins and other substances present in the thyroid gland in addition to iodine [R. 93] and that in the solution which he tested there could be other parts of the thyroid gland in solution.

> "Q. * * * There could, however, be other parts of the thyroid gland solution? A. That is possible" [R. 94].

Thus we believe the Government's own witness has clearly admitted: first, he only tested for the presence of iodine; and, second, that other thyroid substances could be present.

Now we believe it is very clear from the testimony of the Government's own witness Buell that the solution contained within the vial, Ex. 3, was not different from anything which it was purported or represented to possess.

The witness Buell admits:

> "Q. Did you read on there this portion: 'This preparation does not contain any known therapeutically useful constituent'? A. I read that, sir.
>
> Q. Did that indicate to you that there was no active substance of thyroid in that solution? A. Well, you would draw that conclusion from reading that; but I did not let that influence me at all when I made my analysis" [R. 94, 95].

This, we believe, is a vital admission and one which establishes most convincingly that the Government failed to prove its case. The Government's own witness Buell has admitted that he read the notation on the label which stated that the preparation did not contain any "known therapeutically useful constituent" and from that he did draw the conclusion that there was no active substance of thyroid in the solution. In other words, the Government's own witness admitted that from the label he did draw the conclusion that no iodine was present in the solution contained in the vial, Ex. 3.

Not only did the Government fail to prove thyroid substance was not present, but appellants, through the testimony of Bavouset, established by direct testimony as to how the solution was made, and that one grain of thyroid substance for every cubic centimeter of solution was embodied in the solution when it was manufactured.

Bavouset's testimony as to the disclaimer, how the solution was made and what it contained is as follows:

> "* * * We put a disclaimer on that product, stating that it did not contain therapeutically useful constituents, to definitely let the doctor know that the thyroid content was not the iodine content" [R. 111].
>
> "The Court: What do you mean by 'thyroid substance'?
>
> The Witness: You take the powdered thyroid, that is the dessicated thyroid, and put it into a flask containing water, a measured amount of water, and that is extracted by shaking it over a period of time, usually two weeks. That is not continuously shaken, but several times a day, shaken up thoroughly and allowed to stand and then filtered off, and

that material which is soluble in the water is then put into vials, with due process of sterilization, etc." [R. 111].

He also testified that he has been making this product over a period of about fifteen years [R. 110], that doctors request it and it is sold only to doctors [R. 111]. Bavouset also testified that there are many other preparations which specify "thyroid substance" that do not contain any iodine and that such preparations are used daily:

"The Court: Before you leave this thyroid question, I would like to ask the witness: Is there any other article on the market that you know anything about that has a label which specifies 'thyroid substance' that does not contain any iodine?

The Witness: Yes, your Honor; there are many such preparations similar to this one and with thyroid, alone; that is, there is thyroid substance by itself without other materials in with it. There are many such preparations on the market, used daily.

The Court: That contain no iodine?

The Witness: Yes, your Honor.

The Court: Sold to physicians?

The Witness: Yes, your Honor.

Q. By Mr. Stick: Do you have any of those substances? A. Yes, we do" [R. 113].

It should be noted that this product is a sterile solution and sold only to doctors who request it, and that there are many "* * * doctors who claim that there are other activities that can be attributed to thyroid other than the activity of the thyroxin itself" [R. 136].

As Dr. Icke testified, an aqueous extract of thyroid substance merely refers to that material which would be

dissolved by water from the dessicated thyroid gland and that a doctor, looking at the label, would not expect to find thyroxin in the solution:

> "Q. Is there anything on that label which would indicate to a doctor whether that is a water-solution or extraction? A. The very nature of the product itself, the fact that it is a glandular extract, would indicate to him that it is a water-solution.
>
> Q. Would he, looking at that label, expect to find, normally, thyroxin in the solution? A. Certainly not" [R. 177].

There is no testimony whatever of any one being misled by the term "thyroid substance". If a doctor intends to give thyroid active material, namely, thyroxin, he gives it orally, and not by injection. Many gland products are active only by injection, but thyroid is unique in being active by mouth; and a great point of that is made in biochemistry, which every doctor is required to take [R. 178].

Furthermore, in support of this factual testimony, we have the admission by the Government witness Buell that the thyroid is a gland in the body of a living animal; that this gland contains certain compounds; and that *one* of these compounds or substances is iodine or is an iodine compound [R. 92]. The Government witness Buell also admitted, on page 93 of the Record, that there would be in a thyroid gland things other than iodine or thyroxine. Then again, in the record on page 94, after admitting that iodine would not be present in a water solution, that other portions of the thyroid gland could be.

Thus epitomizing the testimony, the Government witness admits: first, that from the label he did draw the

conclusion that no active substance of the thyroid was present, namely, iodine; second, that the only test made was for the presence of iodine; third, that the thyroid gland contains other substances; and, fourth, that these other substances may have been present.

If this actual situation is coupled with the testimony of Bavouset that he put one grain of thyroid substance in each cubic centimeter of the solution, we respectfully submit that not only has the Government failed to prove its case beyond a reasonable doubt, but on the contrary, the *appellants have proved beyond a reasonable doubt* that the proper stated amount of thyroid substance was present.

The Test Made by Mason for Posterior Pituitary Was Inaccurate and Worthless (Counts I and II).

The test made of Ex. 3 (Counts I and II) by Mason for posterior pituitary was inaccurate and worthless. Mason did not take into consideration the fact that the solution, Ex. 3, contained suprarenal cortex which invariably contains adrenalin, and that adrenalin "would repress any tests which were designed to show the presence of posterior pituitary" [R. 179].

The *effect* of *adrenalin is antagonistic to the effect of posterior pituitary,* and the posterior pituitary in Ex. 3 was not allowed to show its presence in the test made by Mason [R. 180]. In other words, adrenalin negatives the effect of posterior pituitary because *posterior pituitary* will *contract smooth muscle* and *adrenalin* will *relax smooth muscle* so that there is an *antagonistic effect* [R. 195].

Although the witness Mason contended that if adrenalin was present in Ex. 1, it would not have interfered with

any assay for posterior pituitary [R. 222], he admitted on page 224 of the Record that the *test* that he made was *not an assay,* and that the only way that the quantity of posterior pituitary present could be determined is by an assay for the presence of posterior pituitary. He further admitted that he had not made any test to determine the relative quantity of epinephrin (adrenalin) present in a given amount of suprarenal cortex [R. 225], and that *if adrenalin were present before you could measure the presence of posterior pituitary by muscular contraction, there would have to be enough posterior pituitary to overcome whatever counter-effect the adrenalin would have* [R. 222].

In connection with POINT ONE, *supra,* we have shown that Mason was biased and gave contradictory testimony.

Conclusion.

The judgment of conviction appealed from should be reversed and the case remanded to the District Court with instructions to enter a verdict of not guilty.

Respectfully submitted,

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